105TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPORT
105–306

FOOD AND NUTRITION INFORMATION REFORM ACT OF 1997

OCTOBER 6, 1997.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. BLILEY, from the Committee on Commerce, submitted the following

R E P O R T

[To accompany H.R. 2469]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, to whom was referred the bill (H.R. 2469) to amend the Federal Food, Drug, and Cosmetic Act and other statutes to provide for improvements in the regulation of food ingredients, nutrient content claims, and health claims, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

CONTENTS

AMENDMENT

The amendments are as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE; REFERENCE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Food and Nutrition Information Reform Act of 1997".

(b) REFERENCE.—Unless otherwise stated, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

(c) TABLE OF CONTENTS.—The table of contents is as follows:

TITLE I—IMPROVING THE REGULATION AND LABELING OF FOOD

SEC. 101. FLEXIBILITY FOR REGULATIONS REGARDING CLAIMS.

Section 403(r)(4) (21 U.S.C. 343(r)(4)) is amended by adding at the end the following:

"(D) Subject to the time period in the last sentence of clause (A)(i), proposed regulations under this paragraph may be made effective upon publication at the discretion of the Secretary, notwithstanding the provisions of section 553 of title 5, United States Code, pending consideration of public comment and publication of a final regulation. Such regulations shall be deemed final agency action for purposes of judicial review.".

SEC. 102. PETITIONS FOR CLAIMS.

Section 403(r)(4)(A)(i) (21 U.S.C. 343(r)(4)(A)(i)) is amended—

(1) by adding after the second sentence the following: "If the Secretary does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner.";

(2) in the fourth sentence (as amended by paragraph (1)) by inserting immediately before the comma the following: "or the petition is deemed to be denied"; and

(3) by adding at the end the following: "If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary issues a proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary. If the Secretary does not issue such a proposed regulation within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the proposed regulation did not occur within such 540 days.".

SEC. 103. HEALTH CLAIMS FOR FOOD PRODUCTS.

Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by adding at the end thereof the following:

"(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made with respect to a food if—

"(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

"(ii) a person has submitted to the Secretary, at least 150 days (during which the Secretary may issue a regulation described in subparagraph (4)(D) and may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature, including a bibliography of such literature, relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

"(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii) and are otherwise in compliance with paragraph (a) and section 201(n); and

"(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

"(D) A claim submitted under the requirements of clause (C) may be made until—

"(i) such time as the Secretary issues a regulation (including a regulation described in subparagraph (4)(D)) under the standard in clause (B)(i)—

"(I) prohibiting or modifying the claim and the regulation has become effective, or

"(II) finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause; or

"(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met.".

SEC. 104. NUTRIENT CONTENT CLAIMS.

Section 403(r)(2) (21 U.S.C. 343(r)(2)) is amended by adding at the end the following:

"(G) A claim of the type described in subparagraph (1)(A) for a nutrient, for which the Secretary has not promulgated a regulation under clause (A)(i), shall be authorized and may be made with respect to a food if—

"(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers;

"(ii) a person has submitted to the Secretary, at least 150 days (during which the Secretary may issue a regulation described in subparagraph (4)(D) and may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature, including a bibliography of such literature, relating to the nutrient level to which the claim refers;

"(iii) the claim and the food for which the claim is made are in compliance with clauses (A) and (B), and are otherwise in compliance with paragraph (a) and section 201(n); and

"(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

"(H) A claim submitted under the requirements of clause (G) may be made until—

"(i) such time as the Secretary issues a regulation (including a regulation described in subparagraph (4)(D))—

"(I) prohibiting or modifying the claim and the regulation has become effective, or

"(II) finding that the requirements of clause (G) have not been met, including finding that the petitioner had not submitted all the information required by such clause; or

"(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (G) have not been met.".

SEC. 105. REFERRAL STATEMENTS.

Section 403(r)(2)(B) (21 U.S.C. 343(r)(2)(B)) is amended to read as follows:

"(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food, and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related, then the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: 'See nutrition information for ____ content.' The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in this clause, the Secretary shall take into account the significance of the food in the total daily diet.".

SEC. 106. DISCLOSURE OF IRRADIATION.

Chapter IV (21 U.S.C. 341 et seq.) is amended by inserting after section 403B the following:

"DISCLOSURE

"SEC. 403C. (a) No provision of section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).

"(b) In this section, the term 'radiation disclosure statement' means a written statement or symbol that discloses that a food or a component of the food has been intentionally subject to radiation.".

SEC. 107. IRRADIATION PETITION.

Not later than 60 days following the date of the enactment of this Act, the Secretary of Health and Human Services shall—

(1) make a final determination on any petition pending with the Food and Drug Administration that would permit the irradiation of red meat under section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act; or

(2) provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate an explanation of the process followed by the Food and Drug Administration in reviewing the petition referred to in paragraph (1) and the reasons action on the petition was delayed.

SEC. 108. GLASS AND CERAMIC WARE.

(a) IN GENERAL.—The Secretary may not implement any requirement which would ban, as an unapproved food additive, lead and cadmium based paints in the lip and rim area of glass and ceramic ware before the expiration of one year after the date such requirement is published.

(b) LEAD AND CADMIUM BASED PAINT.—Lead and cadmium based paint may not be banned as an unapproved food additive if it is on glass and ceramic ware—

(1) which has less than 60 millimeters of decorating area below the external rim; and

(2) which is not, by design, representation, or custom of usage intended for use by children.

SEC. 109. FOOD CONTACT SUBSTANCES.

(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 348(a)) is amended—

(1) in paragraph (1)—

(A) by striking "subsection (i)" and inserting "subsection (j)"; and

(B) by striking at the end "or";

(2) by striking the period at the end of paragraph (2) and inserting "; or";

(3) by inserting after paragraph (2) the following:

"(3) in the case of a food additive that is a food contact substance, there is—

"(A) in effect for such substance a regulation issued under this section prescribing the conditions under which such substance may be safely used and such substance and the use of such substance are in conformity with such regulation; or

"(B) a notification submitted under subsection (h) that is in effect."; and

(4) in the flush matter following paragraph (3) (as added by paragraph (3)), by inserting "or notification" after "regulation" each place it appears.

(b) NOTIFICATION FOR FOOD CONTACT SUBSTANCES.—Section 409 (21 U.S.C. 348), as amended by subsection (a), is further amended—

(1) by redesignating subsections (h) and (i), as subsections (i) and (j), respectively;

(2) by inserting after subsection (g) the following:

"Notification Relating to a Food Contact Substance

"(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a person manufacturing or supplying a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the—

"(A) name of the person;

"(B) identity and intended use of the food contact substance; and

"(C) determination of the person that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A).

The notification shall contain the information that forms the basis of the determination and all information required to be submitted by regulations promulgated by the Secretary.

"(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless, within the 120-day period, the Secretary—

"(i) makes a determination that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), or

"(ii) makes a determination under paragraph (3) with respect to the need for a petition under subsection (b) for such food contact substance,

and informs the person of such determination.

"(B) A determination by the Secretary under subparagraph (A)(i) shall constitute final agency action subject to judicial review.

"(C) A notification under this subsection shall be effective only with respect to the person identified in the notification.

"(3)(A) The notification process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and the person manufacturing or supplying the food contact substance agree that such person should submit a petition under subsection (b).

"(B) The Secretary may promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b) and shall consider criteria such as the probable consumption of a food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (b) with respect to the food contact substance.

"(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

"(5) In this section, the term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.";

(3) in subsection (i), as so redesignated by paragraph (1), by adding at the end the following: "The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to be no longer in effect."; and

(4) in subsection (j), as so redesignated by paragraph (1), by striking "subsections (b) to (h)" and inserting "subsections (b) to (i)".

(c) EFFECTIVE DATE.—Notifications under section 409(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), may be submitted beginning 18 months after the date of enactment of this Act.

SEC. 110. MARGARINE.

(a) SECTION 301(m).—Paragraph (m) of section 301 (21 U.S.C. 331) is amended by striking "section 407(b) or 407(c)" and inserting "section 407".

(b) SECTION 407.—Section 407 (21 U.S.C. 347) is amended to read as follows:

"OLEOMARGARINE AND MARGARINE

"SEC. 407. No person shall sell, or offer for sale, oleomargarine or colored margarine unless the principal display panel of such oleomargarine or margarine bears as one of its principal features the word 'oleomargarine' or 'margarine' which is in—

"(1) bold type on such panel;

"(2) a size reasonably related to the most prominent printed matter; and

"(3) lines generally parallel to the base on which the package rests as it is designed to be displayed.".

(c) ACT OF MARCH 16, 1950.—Sections 3(a) and 6 of the Act of March 16, 1950 (21 U.S.C. 347a, 347b) are repealed.

TITLE II—EFFECTIVE DATE

SEC. 201. EFFECTIVE DATE.

The amendments made by this Act shall take effect on the date of the enactment of this Act.

Amend the title so as to read:

A bill to amend the Federal Food, Drug, and Cosmetic Act and other statutes to provide for improvements in the regulation of food, nutrient content claims, and health claims, and for other purposes.

PURPOSE AND SUMMARY

The purpose of H.R. 2469, the Food and Nutrition Information Reform Act of 1997, is to enhance consumer knowledge of the health benefits of foods and food treatments by updating the statute, reducing decision-making times, and improving the processes by which information can be communicated to consumers that will enable them to adopt more healthful diets.

BACKGROUND AND NEED FOR LEGISLATION

H.R. 2469, the Food and Nutrition Information Reform Act of 1997, is a compilation of common-sense reforms pertaining to existing statutory and regulatory requirements on the labeling of food products. In order to expand consumer access to important dietary information, these reforms focus on a number of problems which are summarized below.

As a result of the procedural requirements of the Administrative Procedures Act and the Nutrition Labeling and Education Act, it often takes an estimated two years following submission of a health or nutrient content claim petition before the Food and Drug Admin-

istration (FDA) is able to approve a claim, thereby delaying the provision of important dietary information to consumers. In addition, there currently exists no time limit within which the FDA is to take final action on petitions for health and nutrient content claims. Instead, current law only requires the FDA to deny a claim petition or issue a proposed rule authorizing the claim within 190 days. Earlier this year, the U.S. District Court for the Southern District of New York ruled in the case of *Nutritional Health Alliance* v. *Shalala,* 953 F. Supp. 526 (S.D.N.Y. 1997), that this lack of a timeframe for a final rule violates First Amendment protections. It also ordered the Secretary of Health and Human Services (the Secretary) to establish an appropriate deadline for agency action on petitions, which the FDA has internally (and flexibly) set as 270 days following the proposed rule.

With regard to health and nutrient content claims, several obstacles exist to enhanced consumer education. Under the Nutrition Labeling and Education Act of 1990, a health claim may be made only in those instances where the Secretary has promulgated a regulation permitting such a claim to be made. Health claims include statements about such diet/disease relationships as calcium and osteoporosis, and folic acid and neural tube defects. To date, the FDA has allowed claims for only ten different diet/disease relationships. The perception of a time-consuming process without predictability of end point is widely believed to serve as a disincentive to the proposal of new claims.

Similarly, nutrient content claims may be made only in those instances where the Secretary has promulgated a regulation setting forth the daily value or nutrient specific level upon which a nutrient content claim may be made. Since the making of such claims is limited solely to those nutrients which the FDA has already authorized, important information that can benefit diet-conscious consumers cannot be communicated to them. For example, a product cannot advise consumers that it is "high in soluble fiber" because the FDA has not yet promulgated a regulation for that nutrient specifying a nutrient level for soluble fiber.

Additional outdated requirements complicate the provision of helpful dietary information to consumers. For example, under existing law, nutrient content claims must be accompanied by a referral statement ("See back panel for nutrition information"). Although this labeling requirement served a purpose at one time by alerting consumers about the presence and location of nutrient information, such notice is no longer needed. Mandatory nutrition information has been present on virtually all food labels for several years, and consumers are aware of their presence and location. As a result, this type of statement is viewed by many as no longer necessary.

Another such example pertains to irradiation. Currently, food products treated with irradiation to remove harmful bacteria, parasites, mold and fungus (which, in the U.S., include such agricultural products as poultry, spices, and certain fruits and vegetables) are required to post a notice to consumers, including an irradiation graphic, that is more prominent than the product's ingredients listing. There is a growing concern among producers, consumer safety experts, and academics, however, that this type of disclosure may

frighten consumers away from products that may benefit from this treatment.

Procedures utilized by the Food and Drug Administration to process and review applications for approval of certain types of packaging also need updating. At present, petitions for marketing approval of substances that come into contact with foods (such as plastic wrap) are reviewed by the same individuals charged with the responsibility for review of direct food additive petitions. As a result, the backlog on indirect additive petitions has approached nearly two hundred.

Finally, current regulations relating to margarine are also antiquated and in need of reform. These requirements, which originally were promulgated to ensure that colored margarine would not be confused with butter, include prohibitions on the sale of margarine in packaging larger than one pound, overly detailed labeling restrictions, and consumer notice specifications for food service establishments where margarine is served.

HEARINGS

The Committee on Commerce has not held hearings on H.R. 2469. However, in preparation for action on modernization of the Food and Drug Administration, the Committee held 17 hearings on reform of the FDA over the last 30 months.

COMMITTEE CONSIDERATION

On September 17, 1997, the Subcommittee on Health and Environment met in an open markup session and approved H.R. 2469 for Full Committee consideration, amended, by a voice vote. On September 25, 1997, the Full Committee met in an open markup session and ordered H.R. 2469, reported to the House, amended, by a rollcall vote of 43 yeas to 0 nays.

ROLLCALL VOTES

Clause 2(l)(2)(B) of rule XI of the Rules of the House requires the Committee to list the recorded votes on the motion to report legislation and amendments thereto. The following are the recorded votes on the motion to report H.R. 2469 and on amendments offered to the measure, including the names of those Members voting for and against.

COMMITTEE ON COMMERCE -- 105TH CONGRESS
ROLL CALL VOTE #47

BILL: H.R. 2469, Food and Nutrition Reform Act of 1997

MOTION: Motion by Mr. Bliley to order H.R. 2469, reported to the House, amended.

DISPOSITION: AGREED TO, by a roll call vote of 43 yeas to 0 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Bliley	X			Mr. Dingell	X		
Mr. Tauzin	X			Mr. Waxman			
Mr. Oxley	X			Mr. Markey	X		
Mr. Bilirakis	X			Mr. Hall	X		
Mr. Schaefer	X			Mr. Boucher			
Mr. Barton	X			Mr. Manton	X		
Mr. Hastert				Mr. Towns	X		
Mr. Upton	X			Mr. Pallone	X		
Mr. Stearns				Mr. Brown	X		
Mr. Paxon	X			Mr. Gordon			
Mr. Gillmor	X			Ms. Furse	X		
Mr. Klug	X			Mr. Deutsch	X		
Mr. Greenwood	X			Mr. Rush	X		
Mr. Crapo	X			Ms. Eshoo	X		
Mr. Cox				Mr. Klink	X		
Mr. Deal	X			Mr. Stupak	X		
Mr. Largent	X			Mr. Engel	X		
Mr. Burr	X			Mr. Sawyer	X		
Mr. Bilbray	X			Mr. Wynn	X		
Mr. Whitfield	X			Mr. Green	X		
Mr. Ganske	X			Ms. McCarthy	X		
Mr. Norwood	X			Mr. Strickland	X		
Mr. White	X			Ms. DeGette	X		
Mr. Coburn	X						
Mr. Lazio							
Mrs. Cubin	X						
Mr. Rogan							
Mr. Shimkus	X						

9/25/97

COMMITTEE ON COMMERCE—105TH CONGRESS

VOICE VOTES—SEPTEMBER 25, 1997

Bill: H.R. 2469, Food and Nutrition Information Reform Act of 1997.

Amendment: Amendment in the Nature of a Substitute by Mr. Whitfield.

Disposition: Agreed To, amended, by a voice vote.

Amendment: Amendment to the Whitfield Amendment in the Nature of a Substitute by Mr. Stupak re: establishment of an expedited food contact substance petition review process.

Disposition: Agreed To, by a voice vote.

Amendment: Amendment to the Whitfield Amendment in the Nature of a Substitute by Mr. Klink re: delay in the effectiveness of, and a limitation on, restrictions relating to decorative glass and ceramic ware.

Disposition: Agreed To, by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, the Committee has not held oversight or legislative hearings on this legislation.

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform and Oversight with respect to this legislation. However, on December 21, 1995, the Committee on Government Reform and Oversight submitted a report to the House entitled "The FDA Food Additive Review Process: Backlog and Failure to Observe Statutory Deadline" (H. Rpt. 104–436), which concerned issues addressed in H.R. 2469.

NEW BUDGET AUTHORITY AND TAX EXPENDITURES

In compliance with clause 2(l)(3)(B) of rule XI of the Rules of the House of Representatives, the Committee finds that H.R. 2469 would result in no new or increased budget authority or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 403 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 2(l)(3)(C) of rule XI of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 403 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, October 1, 1997.

Hon. TOM BLILEY,
Chairman, Committee on Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2469, the Food and Nutrition Information Reform Act of 1997.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Cynthia Dudzinski.

Sincerely,

JUNE E. O'NEILL, *Director.*

Enclosure.

H.R. 2469—Food and Nutrition Information Reform Act of 1997

Summary: H.R. 2469 would change parts of the process of regulating food ingredients and claims related to the nutritional content and healthy effects of food, and would provide avenues for approval outside of the petition processes currently required. In addition, it would expedite the issuance of final rules promulgated by the Food and Drug Administration (FDA) in response to petitions and require the completion of action on a pending claim regarding the radiation of red meat.

The bill would result in additional costs to the FDA, but CBO cannot estimate the amount of such costs, which would be subject to appropriation action. Because H.R. 2469 would not affect direct spending or receipts, pay-as-you-go procedures would not apply. The bill contains no intergovernmental mandates, and would improve no costs on state, local, or tribal governments. While it would impose a mandate on the private sector, the costs of carrying out that mandate would be negligible.

Estimated Cost to the Federal Government: CBO cannot estimate the cost of implementing this bill because we do no have sufficient information to project the cost of provisions regarding food contact substances.

Basis of Estimate: For the purposes of this estimate, CBO assumes that all amounts authorized in H.R. 2469 would be appropriated by the start of each fiscal year and that outlays would follow the historical spending patterns of the Food and Drug Administration. The costs of this legislation fall within budget function 550 (Health).

Flexibility for Regulations Regarding Claims.—Under H.R. 2469, regulations published by the Secretary regarding claims about the level of a nutrient in a food item or about the relationship of a nutrient to a health-related condition would be effective for a limited time while they were awaiting pubic review and final regulation. CBO estimates no cost for these provisions because the FDA would not be required to take any additional action.

Petitions for Claims.—Under current law, the Secretary is required to act on a petition within a specified amount of time. Under the bill, petitions not acted upon within the time limits would be denied unless an extension were agreed upon between the Secretary and the petitioner. According to the FDA, the Secretary is

already meeting these deadlines, so there would be no additional costs as a result of this provision.

In addition, in cases where the Secretary issues a proposed regulation in response to a petition, the bill would require the rulemaking process to be completed within 540 days of the date the petition was received by the Secretary. Any regulation that exceeded this deadline would be considered final. To date, there have been only two regulations that became final rules, and both took longer than 540 days to complete the process. According to the FDA, one and a half additional full-time employees would be necessary to complete the regulations within the deadline and to publish as final rules those regulations not meeting the 540-day deadline. CBO estimates that the additional staff would cost an additional $1 million over the 1988–2002 period.

Health Claims for Food Products and Nutrient Content Claims.—The bill would permit claims to be made on food labels concerning the level of a nutrient or its relationship to a health condition without the Secretary's authorization, provided the claim met specific conditions. These conditions include existence of an authorization statement by the National Academy of Sciences or other qualified scientific entity in support of the claim, notification of the FDA 150 days before the claim is published, and submission of a balanced representation of the scientific literature relating to the claim. A claim would be valid until a regulation issued by the Secretary regarding it became effective or until the Secretary or U.S. district court determined that the requirements of this provision had not been met. Based on information from the FDA, CBO estimates handling the new submission process would cost less than $1 million over the 1988–2002 period.

Irradiation Petition.—Within sixty days of enactment, the bill would require FDA to complete all pending petitions regarding the radiation of red meat. Otherwise, the Secretary must report to the House of Commerce and Senate Labor and Human Resources Committees the reason why action on any incomplete petition was delayed. According to the FDA, there is only one such petition currently pending and the agency has made completion of the work on this petition a high priority. Given the level of effort already devoted to this project, enactment of this provision would not likely subject the agency to significant additional costs. If the sixty-day deadline were not met, however, there would be a small cost associated with the additional responsibility of preparing the report.

Food Contact Substances.—Currently in most cases, any food contact substance—a substance intended to contact food but not to have any chemical effect on it—may be marketed only after the FDA has promulgated a regulation permitting its use in response to a petition submitted to the agency. The bill would provide for a notification system that is quicker and simpler than the petition process and that would apply only to the substance that was the specific subject of the notification. While the new process would be simpler to administer, it could attract additional applications necessitating additional resources to be devoted to this approval process. However, CBO cannot estimate the magnitude of these costs at this time.

Pay-as-you-go Considerations: None.

Estimated Impact on State, Local, and Tribal Governments: H.R. 2469 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act of 1995 and would impose no costs on state, local, or tribal governments.

Estimated Impact on the Private Sector: H.R. 2469 would abolish several existing private-sector mandates and impose a new mandate on sellers of colored oleomargarine and margarine. CBO estimates that the direct costs of the new mandate would most likely be less than the costs of the existing private-sector mandates that would be replaced. In addition, the bill would make an existing mandate related to nutrient food claims less burdensome.

Under current law, the sale or offering for sale of colored oleomargarine or margarine, or the possession of those products in a form ready for serving, is prohibited if the products do not meet certain labeling, packaging, weight, and restaurant notification requirements. Section 109 of H.R. 2469 would abolish these requirements and impose a new labeling requirement on sellers of colored oleomargarine or margarine. Because current regulations already require extensive labeling for these products, CBO estimates that the cost of the new labeling requirement would be negligible.

Section 105 of the bill would amend an existing private-sector mandate to be less burdensome. Under current law, nutrient food claims are subject to a labeling requirement. Under the bill, the labeling requirement would apply only if the Secretary makes a determination that the food contains a nutrient at a level that increases risk of a disease or health-related condition that is diet-related.

Estimate Prepared By: Federal Cost: Cynthia Dudzinski. Impact on State, Local, and Tribal Governments: Leo Lex. Impact on the Private Sector: Anna Cook.

Estimate Approved By: Robert A. Sunshine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or

accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

SEC. 1. SHORT TITLE; REFERENCE; TABLE OF CONTENTS

The short title for this Act is the "Food and Nutrition Information Act of 1997." All references are to sections or provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 321 et seq.), unless otherwise specified.

TITLE I—IMPROVING THE REGULATION AND LABELING OF FOOD

Sec. 101. Flexibility for regulations regarding claims

This section amends Sec. 403(r)(4) of the FFDCA to allow proposed regulations on claims to become effective upon publication, at the discretion of the Secretary, pending consideration of public comment and publication of a final regulation. Such regulations would be considered final agency action for purposes of judicial review.

This provision is intended to enable the Food and Drug Administration to permit nutrient content claims and health claims to be made as soon as a regulation proposing to authorize their use would be published. This would help expedite the communication to consumers of information on nutritional and health benefits through food labeling. This also would enable the FDA to take prompt action as necessary to address necessary changes in labeling. It is the Committee's intention that the FDA will use this authority primarily for the purpose of expediting reviews of petitions for health and nutrient content claims based on authoritative statements (petitions processed under sections 103 and 104 of this legislation).

The Committee requests the Secretary, in keeping with this legislation's focus on improved FDA performance, to consider the creation of the position of Chief Operating Office at the agency. Such a role could facilitate the administration of the agency's operations, with possible responsibilities including the establishment of standards of performance, determination of performance reviews and employee compensation, and oversight of audits of the performance of reviewers at the FDA.

Sec. 102. Petitions for claims

This section amends Sec. 403(r)(4) of the FFDCA to provide that if the Secretary does not act within 100 days after a claims petition is received, it would be considered to be denied, unless the Secretary and petitioner have reached a mutual agreement on an extension. In addition, if the Secretary does not propose a regulation authorizing a claim or denying a petition within 90 days after deciding to file the petition, it is considered to be denied, unless there is a mutually agreed upon extension. Further, if the Secretary issues a proposed regulation for a petition, the final rules are to be completed within 540 days (18 months) of receiving the petition, a period of time the Committee believes is the maximum reasonable

time necessary to complete final rulemaking. If final rulemaking is not completed within 540 days, the Secretary is required to provide to the House Committee on Commerce and the Senate Committee on Labor and Human Resources the reasons the final rulemaking was not completed within that time period.

This provision is intended by the Committee to serve as a response to the FDA's failure to review health and nutrient content claims within a reasonable period. In addition, the Committee notes the ruling of the U.S. District Court for the Southern District of New York in *Nutritional Health Alliance* v. *Shalala*, 953 F. Supp. 526 (S.D.N.Y. 1997), which directed that a deadline be established within which the FDA would be required to act on health claim petitions. The legislation establishes a deadline for both nutrient content and health claim petitions requiring the FDA to complete rulemaking within 540 days of the date the petition is received by the agency.

Sec. 103. Health claims for food products

This section amends Sec. 403(r)(3) of the FFDCA by adding a section that allows a health claim which is not otherwise authorized in a regulation by the Secretary to be made under the following conditions. First, the claim would be allowed if a specified scientific body has published an authoritative statement, currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers. The provision specifies such governmental bodies as the National Institutes of Health and the Centers for Disease Control and Prevention, as well as the National Academy of Sciences. The Committee intends this process to enable the Secretary to permit claims based on such statements in order that consumers will be assisted in maintaining healthy dietary practices.

Second, at least 150 days before a food labeled with the new claim is first introduced into interstate commerce, the manufacturer making the claim must notify the Secretary. A claim that meets the requirements of this provision could be made until the Secretary issues a regulation, that has become effective, that either prohibits or modifies the claim or finds that the requirements for making the claim have not been met, or a U.S. district court determines that the requirements for making the claim have not been met.

The claim notification must include the exact wording of the claim, a concise description of the basis for determining that the claim meets the requirements of an authoritative statement, a copy of the specific statement being relied on to make the claim, and a balanced representation of the scientific literature related to the relationship between the nutrient and a disease or health-related condition to which the claim refers. The purpose of this requirement is to facilitate the Secretary's determination whether the authoritative statement upon which the notification is based is supported by scientific consensus to the extent the Secretary considers appropriate to allow the claim.

In addition, the claim and the food on which it appears must also be in compliance with other applicable rules, and the claim must be stated in a manner that is an accurate representation of the au-

thoritative statement on which it is based and that will enable consumers to comprehend the relative significance of the claim in the context of a total daily diet. Finally, the statement on which the claim is based would be considered to be authoritative only if it is published by the scientific body and is not simply a statement of an employee of the body made in an individual capacity.

The Committee views the history of the folic acid and neural tube defects health claim as important evidence of the need for this provision. In 1992, the Centers for Disease Control and Prevention (CDC) issued the following recommendation to women of childbearing age, aimed at reducing the risk of pregnancies affected by neural tube birth defects: "All women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or [other neural tube defects]." [Centers for Disease Control, 41 Morbidity and Mortality Weekly Report (September 11, 1992)]. The CDC estimated that adherence to this recommendation could reduce the number of cases of spina bifida and other neural tube defects in the United States by 50 percent.

Despite this recommendation, foods containing folic acid could not include on their labels truthful, nonmisleading claims about the folic acid/birth defect connection until the FDA approved the claim through an arduous and costly notice and comment rulemaking procedure. In January 1993, the FDA promulgated a rule prohibiting claims concerning the relationship. In the wake of the controversy that met the FDA's action, and despite the absence of any change in the scientific evidence, the agency reversed course, proposing to authorize such claims in October 1993. Final regulations authorizing the claim were promulgated in March 1996. The Committee has expressed in the past, and remains concerned, that many children may have suffered preventable neural tube defects as a result of this delay in authorizing health claims based on the 1992 CDC recommendation.

The folic acid example is among the earliest illustrations of this problem, and the Committee does not view it as being the only justification for this legislation. Authoritative scientific bodies, as part of their official responsibilities for public health protection, regularly undertake deliberative reviews of the scientific evidence to evaluate potential diet/disease relationships, and issue authoritative statements concerning such relationships. The Committee intends that this provision will establish a presumption of validity with respect to claims that are appropriately based on statements by such authoritative scientific bodies. As a result, a streamlined procedure would be available for the Secretary to permit more scientifically sound nutrition information to be provided to consumers. This provision would thereby prevent a reoccurrence of such problems as the one presented by the folic acid/neural tube defect claim.

Sec. 104. Nutrient content claims

This section makes amendments parallel to those made by section 103 with respect to nutrient content claim provisions. Currently, claims characterizing the level of a nutrient in food (e.g., "only 5 grams . . .") may be made only for nutrients for which

there are established Reference Daily Intakes or Daily Reference Values (together referred to as "Daily Values"). This provision would amend Sec. 403(r)(2) of the FFDCA by adding a provision that allows that a nutrient content claim that is not otherwise authorized in a regulation by the Secretary to be made under the following conditions. First, the claim would be allowed if a specified scientific body has published an authoritative statement which provides a daily value or nutrient level that is currently in effect and serves as a basis for the claim. The provision specifies such governmental bodies as the National Institutes of Health and the Centers for Disease Control and Prevention, as well as the National Academy of Sciences. Second, at least 150 days before the food labeled with the new claim is first introduced into interstate commerce, the manufacturer making the claim must notify the Secretary.

The claim notification must include the exact wording of the claim, a concise description of the basis for determining that the claim meets the requirements of an authoritative statement, a copy of the specific statement being relied on to make the claim, and a balanced representation of the scientific literature relating to the nutrient level to which the claim refers. In addition, the claim and the food on which it appears must also be in compliance with other applicable rules, and the claim must be stated in a manner that is an accurate representation of the authoritative statement on which it is based and that will enable consumers to comprehend the relative significance of the claim in the context of a total daily diet. Finally, the statement on which the claim is based would be considered to be authoritative only if it is published by the scientific body and is not simply a statement of an employee of the body made in an individual capacity. A claim that meets the requirements of this provision could be made until the Secretary issues a regulation, that has become effective, that either prohibits or modifies the claim or finds that the requirements for making the claim have not been met, or a U.S. district court determines that the requirements for making the claim have not been met.

The Committee emphasizes that this provision maintains the full range of existing FDA enforcement powers with respect to claims made in violation of the statutory requirements. In addition, the legislation gives the FDA enhanced rulemaking authority, enabling the agency to promptly ban or modify such claims by issuing proposed regulations that are effective upon the date of publication. It is the Committee's intent that this provision will enable consumers to be more promptly and effectively informed of beneficial levels of nutrients in foods for which Daily Values have not been established. Further, the Committee intends that this process will establish a presumption of validity with respect to claims that are appropriately based on authoritative statements by designated scientific bodies, so that consumers will be assisted in maintaining healthy dietary practices.

As noted above, this section requires a petitioner to provide the Secretary with a balanced representation of the scientific literature relating to the nutrient level to which the claim refers. The purpose of this requirement is to facilitate the Secretary's determination of whether the authoritative statement upon which the petition is based is supported by scientific consensus to the extent the Sec-

retary considers appropriate to allow the claim. It is also intended to ensure that the petition properly references the context within which the authoritative statement is made to ensure that it is accurately used in the claim.

Sec. 105. Referral statements

This section amends Sec. 403(r)(2)(B) of the FFDCA to require that if a nutrient content claim is made for a food, which the Secretary determines contains another nutrient at a level that increases the risk to the general public of a diet-related disease or health-related condition, the label must include a statement that is prominent and in immediate proximity to such claim, which states: "See nutrition information for _____ content." The blank is to identify the nutrient associated with the increased disease or health-related risk. In determining risk associated with a given nutrient under this provision, the Secretary is to take into account the significance of the food in the total daily diet.

Sec. 106. Disclosure of irradiation

Section 106 inserts a new Sec. 403(C) into the FFDCA to provide that no existing provision of the FFDCA could be considered to require a separate radiation disclosure statement that is more prominent than the declaration of ingredients on the food label. For purposes of this section, the term "radiation disclosure statement" refers to any written statement or symbol that discloses that a food or any component of it has been intentionally subjected to radiation.

To ensure the intended effect of this provision during the process of implementation, the Committee directs the Secretary to promptly publish for public comment proposed amendments to current regulations relating to the labeling of foods treated with ionizing radiation. The Committee expects final regulations to be issued not more than 12 months after the date of enactment of this measure. The public comment process should be utilized by the Secretary to provide an opportunity to comment on whether the regulations should be amended to revise the prescribed nomenclature for the labeling of irradiated foods and on whether such labeling requirements should expire at a specified date in the future. The Committee intends for any required disclosure to be of a character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety.

Sec. 107. Irradiation petition

This section requires that within 60 days of enactment, the Secretary make a final determination on any pending food additive petition before the FDA that would permit the irradiation of red meat. If this regulatory decision is not completed in 60 days, the agency is to explain, in writing, to the House Committee on Commerce and the Senate Committee on Labor and Human Resources the process used in reviewing the petition and the reasons that action on the petition has been delayed.

Sec. 108. Glass and ceramic ware

Section 108 delays for one year after publication of applicable guidance relating to glass and ceramic ware the implementation of any requirements that would ban, as an unapproved food additive, either lead- or cadmium-based paints in the lip and rim area of glass and ceramic ware. In addition, lead- and cadmium-based paints would not be banned as unapproved food additives in glass and ceramic ware if they cover less than 60 millimeters of decoration below the external rims of containers not intended for use by children.

Sec. 109. Food contact substances

This section adds a new Sec. 409(h)(1) to the FFDCA which would establish a notification process for the regulation of indirect food additives, known as food contact substances. At least 120 days before a food contact substance is introduced into interstate commerce, a manufacturer or supplier could notify the Secretary of the name, identity, and intended use of the substance and the information on which a designated person has determined that the intended use of the substance is safe. The food contact substance could be introduced into interstate commerce 120 days after the date of receipt by the Secretary of the notification, unless the Secretary has determined during the 120-day period that the substance has not been shown to be safe or that a standard petition is needed. Such a determination of the Secretary would be based on the data and information provided in the notification and would constitute final agency action. Notification under this provision would be effective only with respect to the person identified in the notification.

The notification process under this provision would be used for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a food additive petition is necessary to provide adequate determination of safety. A petition may also be necessary when the Secretary and the person planning to use the substance agree that it should be submitted. The Secretary could promulgate regulations to identify the circumstances under which a petition is to be filed and could consider such criteria as the probable consumption and potential toxicity of the substance in determining the circumstances in which a petition is necessary. The Secretary is required to maintain confidentiality of any information provided in a notification for 120 days after its receipt. Following that 120-day period, the information may be made available to any interested party, except for any trade secret or confidential commercial information. For purposes of this section, the term "food contact substance" means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food, if its use is not intended to have any technical effect in the food. The Secretary is to prescribe, in regulation, the procedure by which a determination will be made that notification is no longer in effect. Notifications under this provision may be submitted to the Secretary beginning 18 months after the date of enactment.

Sec. 110. Margarine

This section amends Sec. 301 of the FFDCA by striking Sec. 407(b) and (c) that concern the current labeling, packaging, and restaurant use of margarine. In addition, Section 110 amends Sec. 407 to eliminate all current requirements related to margarine except that oleomargarine or colored margarine may not be sold unless the package's principal display panel bears as a principal feature the word "oleomargarine" or "margarine" in bold type that is in a size reasonably related to the most prominent printed matter and in lines generally parallel to the base on which the package rests as it is displayed. Under this provision, existing Sections 3(a) and 6 of the Act of March 16, 1950 would be repealed.

This provision codifies for margarine the "statement of identity" regulations that are in place for most food products. Specifically, the provision uses language specifying that the size of the words "margarine" and "oleomargarine" appear in a size reasonably related to the most prominent printed matter on the margarine package label. With respect to margarine, the Committee expects the reasonably related size to be at least half the size of the largest printed matter on a product's label. The Committee notes that this standard for reasonably related type size should not be rigidly applied, or considered a precedent, with respect to foods other than margarine.

TITLE II—EFFECTIVE DATE

Sec. 201. Effective date

Section 201 states that the provisions of this Act would become effective on the date of enactment.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) * * *

* * * * * * *

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of section [407(b) or 407(c)] *section 407*.

* * * * * * *

CHAPTER IV—FOOD

* * * * * * *

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—
(a) * * *

* * * * * * *

(r)(1) * * *
(2)(A) * * *

[(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: "See _____ for nutrition information." In the statement—

[(i) the blank shall identify the panel on which the information described in the statement may be found, and

[(ii) if the Secretary determines that the food contains a nutrient at a level which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, the statement shall also identify such nutrient.**]**

(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food, and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related, then the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: "See nutrition information for ____ content." The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in this clause, the Secretary shall take into account the significance of the food in the total daily diet.

* * * * * * *

(G) A claim of the type described in subparagraph (1)(A) for a nutrient, for which the Secretary has not promulgated a regulation under clause (A)(i), shall be authorized and may be made with respect to a food if—

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers;

(ii) a person has submitted to the Secretary, at least 150 days (during which the Secretary may issue a regulation described in subparagraph (4)(D) and may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food

with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature, including a bibliography of such literature, relating to the nutrient level to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with clauses (A) and (B), and are otherwise in compliance with paragraph (a) and section 201(n); and

(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(H) A claim submitted under the requirements of clause (G) may be made until—

(i) such time as the Secretary issues a regulation (including a regulation described in subparagraph (4)(D))—

(I) prohibiting or modifying the claim and the regulation has become effective, or

(II) finding that the requirements of clause (G) have not been met, including finding that the petitioner had not submitted all the information required by such clause; or

(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (G) have not been met.

(3)(A) * * *

* * * * * * *

(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made with respect to a food if—

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(ii) a person has submitted to the Secretary, at least 150 days (during which the Secretary may issue a regulation described in subparagraph (4)(D) and may notify any person who is making a claim as authorized by clause (C) that such person has

not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature, including a bibliography of such literature, relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii) and are otherwise in compliance with paragraph (a) and section 201(n); and

(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(D) A claim submitted under the requirements of clause (C) may be made until—

(i) such time as the Secretary issues a regulation (including a regulation described in subparagraph (4)(D)) under the standard in clause (B)(i)—

(I) prohibiting or modifying the claim and the regulation has become effective, or

(II) finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause; or

(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met.

(4)(A)(i) Any person may petition the Secretary to issue a regulation under subparagraph (2)(A)(i) or (3)(B) relating to a claim described in subparagraph (1)(A) or (1)(B). Not later than 100 days after the petition is received by the Secretary, the Secretary shall issue a final decision denying the petition or file the petition for further action by the Secretary. *If the Secretary does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner.* If the Secretary denies the petition *or the petition is deemed to be denied*, the petition shall not be made available to the public. If the Secretary files the petition, the Secretary shall deny the petition or issue a proposed regulation to take the action requested in the petition not later than 90 days after the date of such decision. *If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon*

by the Secretary and the petitioner. If the Secretary issues a proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary. If the Secretary does not issue such a proposed regulation within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the proposed regulation did not occur within such 540 days.

* * * * * * *

(D) Subject to the time period in the last sentence of clause (A)(i), proposed regulations under this paragraph may be made effective upon publication at the discretion of the Secretary, notwithstanding the provisions of section 553 of title 5, United States Code, pending consideration of public comment and publication of a final regulation. Such regulations shall be deemed final agency action for purposes of judicial review.

* * * * * * *

DISCLOSURE

SEC. 403C. (a) No provision of section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).

(b) In this section, the term "radiation disclosure statement" means a written statement or symbol that discloses that a food or a component of the food has been intentionally subject to radiation.

* * * * * * *

[OLEOMARGARINE OR MARGARINE

[SEC. 407. (a) Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the same manner and to the same extent to the provisions of this Act as if it had been introduced in interstate commerce.

[(b) No person shall sell, or offer for sale, colored oleomargarine or colored margarine unless—

[(1) such oleomargarine or margarine is packaged,

[(2) the net weight of the contents of any package sold in a retail establishment is one pound or less,

[(3) there appears on the label of the package (A) the word "oleomargarine" or "margarine" in type or lettering at least as large as any other type or lettering on such label, and (B) a full and accurate statement of all the ingredients contained in such oleomargarine, or margarine, and

[(4) each part of the contents of the package is contained in a wrapper which bears the word "oleomargarine" or "margarine" in type or lettering not smaller than 20-point type.

The requirements of this subsection shall be in addition to and not in lieu of any of the other requirements of this Act.

[(c) No person shall possess in a form ready for serving colored oleomargarine or colored margarine at a public eating place unless a notice that oleomargarine or margarine is served is displayed

prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by the ordinary individual being served in such eating place or is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items. No person shall serve colored oleomargarine or colored margarine at a public eating place, whether or not any charge is made therefor, unless (1) each separate serving bears or is accompanied by labeling identifying it as oleomargarine or margarine, or (2) each separate serving thereof is triangular in shape.

[(d) Colored oleomargarine or colored margarine when served with meals at a public eating place shall at the time of such service be exempt from the labeling requirements of section 403 (except (a) and 403 (f)) if it complies with the requirements of subsection (b) of this section.

[(e) For the purpose of this section colored oleomargarine or colored margarine is oleomargarine or margarine having a tint or shade containing more than one and six-tenths degrees of yellow, or of yellow and red collectively, but with an excess of yellow over red, measured in terms of Lovibond tintometer scale or its equivalent.**]**

OLEOMARGARINE AND MARGARINE

SEC. 407. No person shall sell, or offer for sale, oleomargarine or colored margarine unless the principal display panel of such oleomargarine or margarine bears as one of its principal features the word "oleomargarine" or "margarine" which is in—

(1) bold type on such panel;

(2) a size reasonably related to the most prominent printed matter; and

(3) lines generally parallel to the base on which the package rests as it is designed to be displayed.

* * * * * * *

FOOD ADDITIVES

Unsafe Food Additives

SEC. 409. (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 402(a), unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection **[**(i)**]** *(j)* of this section; **[**or**]**

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used**[**.**]***; or*

(3) in the case of a food additive that is a food contact substance, there is—

(A) in effect for such substance a regulation issued under this section prescribing the conditions under which such substance may be safely used and such substance and the

use of such substance are in conformity with such regulation; or

(B) a notification submitted under subsection (h) that is in effect.

While such a regulation *or notification* relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation *or notification*, be considered adulterated within the meaning of clause (1) of section 402(a).

* * * * * * *

Notification Relating to a Food Contact Substance

(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a person manufacturing or supplying a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the—

(A) name of the person;

(B) identity and intended use of the food contact substance; and

(C) determination of the person that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A).

The notification shall contain the information that forms the basis of the determination and all information required to be submitted by regulations promulgated by the Secretary.

(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless, within the 120-day period, the Secretary—

(i) makes a determination that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), or

(ii) makes a determination under paragraph (3) with respect to the need for a petition under subsection (b) for such food contact substance,

and informs the person of such determination.

(B) A determination by the Secretary under subparagraph (A)(i) shall constitute final agency action subject to judicial review.

(C) A notification under this subsection shall be effective only with respect to the person identified in the notification.

(3)(A) The notification process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and the person manufacturing or supplying the food contact substance agree that such person should submit a petition under subsection (b).

(B) The Secretary may promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b) and shall consider criteria such as the probable consumption of a

food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (b) with respect to the food contact substance.

(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

(5) In this section, the term "food contact substance" means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

Amendment or Repeal of Regulations

[(h)**]** *(i)* The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations. *The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to be no longer in effect.*

Exemptions for Investigational Use

[(i)**]** *(j)* Without regard to subsections (b) to **[**(h)**]** *(i)*, inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

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ACT OF MARCH 16, 1950

AN ACT To regulate oleomargarine, to repeal certain taxes relating to oleomargarine, and for other purposes.

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SEC. 3. **[**(a) The Congress hereby finds and declares that the sale, or the serving in public eating places, of colored oleomargarine or colored margarine without clear identification as such or which is otherwise adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act depresses the market in interstate commerce for butter and for oleomargarine or margarine clearly identified and neither adulterated nor misbranded, and constitutes a burden on interstate commerce in such articles. Such burden exists, irrespective of whether such oleomargarine or margarine originates from an interstate source or from the State in which it is sold.**]**

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[SEC. 6. Nothing in this Act shall be construed as authorizing the possession, sale, or serving of colored oleomargarine or colored margarine in any State or Territory in contravention of the laws of such State or Territory.]

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